American Association of Child & Adolescent Psychiatry

July 7, 2023

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Mike Crapo
Ranking Member
Committee on Finance
U.S. Senate
Washington, D.C. 20510

Dear Chair McMorris Rodgers and Ranking Member Crapo:

On behalf of the American Association of Child and Adolescent Psychiatry (AACAP) and the more than 10,000 child and adolescent psychiatrists, fellows, residents, and medical students that we represent, I am writing in response to your request for information (RFI) to share the child and adolescent psychiatry perspective on how the ongoing stimulant medication shortage continues to affect our members and their patients.

There has been a pediatric mental health crisis for the past few years, leading AACAP, the American Academy of Pediatrics, and the Children's Hospital Association to declare a National State of Emergency[1] in children's mental health. The mental health delivery system for children is already in crisis and the ongoing stimulant medication shortage has only exacerbated the difficulties in accessing treatment for a large number of our patients.

Since October 2022, the United States has experienced a shortage in stimulant medication, starting with the Adderall shortage, linked to Teva manufacturing delays. Many child and adolescent psychiatrists, general psychiatrists, and other physicians have been forced to switch their patients' medications, transitioning them to non-Adderall stimulant alternatives, which has its own set of potential pitfalls, including not working as well to curb symptoms of attention-deficit/hyperactivity disorder (ADHD) and commonly occurring comorbid mental disorders. The increased demand for non-Adderall medications has subsequently created shortages of other types of stimulant medications, including Ritalin and Concerta, leaving few options for patients and their families.

How would you define the scope and impact of the recent and ongoing U.S. drug shortages? What are the impacts of recent and recurring shortages of generic and other critical medicines on patient care?

The consequences of the shortage have been deeply felt by AACAP members, the children and adolescents that they treat, and their families. The disruption to the daily lives of children and their families cannot be overstated. Many patients are decompensating because the medication that they were stable on is no longer available. Untreated ADHD can lead to mental and behavioral disorders, including mood and substance use disorders, unintended injuries resulting from ADHD-related impulsivity, and long-term impacts on relationship-building, educational achievement, and professional success.

[1] Declaration_National_Crisis_Oct-2021.pdf (aacap.org)

Parents and families are also negatively impacted by the disruption untreated ADHD can cause in the home, school, and work environments. Caregivers are forced to compromise on preferred pharmacy selection, medication preference, out-of-pocket costs, and professional and familial obligations in order to fill their child's prescription. A pharmacy's supply is often depleted by the time that a parent gets to a pharmacy, which sets into motion a looping cycle of parent-to-prescriber-to-pharmacist search for medication supply. The cycle repeats itself when monthly refills are necessary and when health plans impose preauthorization requirements or other coverage limitations. Families, whose resources are already stretched thin, often find themselves spending an inordinate amount of time locating a pharmacy for their child's next prescription refill, managing their child's deteriorating behavior and mood, and worrying over lost workdays to care for children, in some cases, who are no longer able to attend school. These challenges are particularly difficult for families with limited financial and other supports. Our members often have to reissue prescriptions numerous times for their patients' refills, in addition to helping families locate available supplies at pharmacies in their region.

What market and economic conditions undermine pharmaceutical supply chains or the availability of drugs?

As we understand it, there are a limited number of manufacturers of stimulant medications, and this is especially true for generic versions of these medications. Any disruption in the supply chain, or increase in demand, can cause a ripple effect in the marketplace. In addition, we have heard from AACAP members that the pharmacies themselves may be contributing to the problem by choosing not to fill prescriptions provided in connection with telehealth visits or choosing not to fill prescriptions written outside of very specific geographic areas, effectively making up their own rules. Lastly, there are set quotas, determined annually, for the raw materials used to make stimulant medications that have the potential to be in short supply before the year's end. It is difficult to untangle the multiple factors that created the stimulant shortage, but more needs to be done, from every angle, to resolve it.

What are the regulatory challenges to manufacturing drugs in the United States, as compared to other countries? Please specify which agency issued and enforced such regulations.

AACAP understands that there are rules in place dictating quotas of raw materials for stimulant manufacturing and allotments of medications provided to pharmacies, and that prescriptions for all types of stimulant medications have increased over the last few years. The supply chain issue is also complex, involving the Drug Enforcement Agency (DEA), the Food and Drug Administration (FDA), and private companies. Medications that are made in other countries must be inspected before entering the U.S. market, which can contribute to the medication shortages.

The FDA is able to take a number of steps to help mitigate a medication shortage that include determining if alternate manufacturers have the ability to increase production, notify affected parties, such as hospitals and pharmacies about impending shortages so that plans can be made to obtain alternate sources of inventory, work with manufacturers to ensure adequate investigation into the root cause of shortages, and review possible risk mitigation measures for the remaining inventory. FDA can also approve new stimulant manufacturers to increase overall stimulant

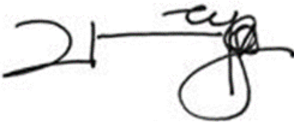
medication production. In turn, the DEA can increase quotas for the raw materials used in manufacturing to support increased production.

Given that supply chain issues can trigger manufacturing delays and disruptions that result in shortages, are further incentives necessary to address manufacturing issues?
In addition to raw material quotas, there is also confusion among practitioners and pharmacists in the field about regulations governing manufacturing, prescribing, and dispensing related to controlled substances like Adderall. Unfortunately, there are current disincentives to enter the marketplace, as it pertains to stimulant medications. Companies in this space are very concerned about violations of policy and potential litigation. The FDA and DEA could work together to develop appropriate policies to help new manufacturers enter the marketplace, while at the same time, ensuring public safety.

AACAP has also gathered several recent examples from child and adolescent psychiatrists around the country, demonstrating the impact of the ongoing stimulant shortage on children and their families, included below. These cases clearly demonstrate the hardships created by this situation.

AACAP appreciates the opportunity to provide input as your respective Committees consider how Congress can understand the drivers of medication shortages and potential policy solutions to bolster patient access. If you have any questions, please contact Alexis Geier-Horan, Chief of Advocacy and Practice Transformation at ahoran@aacap.org, and Ben Melano, Deputy Director of Federal Affairs at bmelano@aacap.org.

Respectfully,



Warren Y. K. Ng, MD, MPH
President

Cc:
The Honorable Frank Pallone, Ranking Member, House Energy & Commerce Committee
The Honorable Ron Wyden, Chairman, Senate Finance Committee

The Impact of Stimulant Shortages on Patients: Cases from Members

Case 1: At an appointment on 1/26/23 parents reported having trouble filling a previous prescription for Concerta 27 mg at the local pharmacy. They paid for it out of pocket on the spot at the pharmacy instead of contacting me out of fear of going without the medication. They could not afford to take more time locating the medication. They also stated they cannot leave work to pick up their 10-year-old son from school if he misbehaves or is suspended during the day. Historically he has high levels of impulsivity which can cause significant safety concerns. For example, within the past 1 year, he impulsively reached for a burning candle on the countertop before anyone could intervene and accidentally set his clothes on fire, resulting in deep second and third degree burns which required hospitalization and skin grafts. In his school program when unmedicated he has eloped from the classroom and has run out to the busy parking area placing himself at risk. He also climbs and jumps from heights without thinking about safety.

The family had purchased the medication from Walmart. I contacted a Walmart pharmacist who told me that Fidelis insurance would only allow specific drug manufacturers to supply the Concerta/MPH ER and they did not have any in their warehouse. They had explained this to the parents, and this is why the parents opted to pay for the non-preferred manufacturer out of pocket. This is not a sustainable practice for a family with limited income even with a coupon which was applied. I was advised to try sending this month's prescription to CVS. I therefore sent the next stimulant prescription to the local CVS on 1/26. When CVS tried to fill it, they told the parents it would need prior authorization because they also did not have the correct manufacturer in stock. I tried to complete a prior authorization for the medication that was available at CVS but by the time I had sent it in to the insurance company, etc., the pharmacy had already run out of their supply. On 2/2 the family asked me to send the script to the local Rite Aid. On 2/3 parent contacted me to let me know that Rite Aid did have medication, but they could not fill script because CVS had already billed their insurance for the script even though they did not fill/dispense.

Since the family had contacted me after my practice hours ended Friday and did not use emergency number, I contacted the CVS pharmacy first thing Monday morning. It took two additional phone calls (one to Rite Aid and then again to the family) in order to ensure that everything was settled. The family was finally able to get script filled on 2/6. During this time, the boy went without his medication for two school days and parents elected to keep him out of school on those days (2/3 and 2/6) for fear that he would be too disruptive to the learning environment without his medication (as is historically the case). The boy stayed with his grandfather during the day while out of school but missed out on being educated and socialized and part of his special education program on those days.

Case 2: Parent contacted me concerned that they could not get Concerta 36 mg for their 10-year-old who has recently been moved to a district based special education classroom instead of a self-contained center-based classroom. They were worried that without the medication their child would become aggressive, disruptive, and possibly get kicked out of the placement and have to return to the self-contained building and experience this as a failure. The parents have limited resources so could not travel far by car to get to another pharmacy. Fidelis/Medicaid insurance limited the options to pharmacies with the correct manufacturer near either her home or near

where her husband was employed. The prescription was canceled and resent three times, each to a different local pharmacy. After the second resend, I instructed the parent to try to contact the pharmacy and ensure that they had medication in stock and then to send me a text message to let me know exactly where to send the script. The message to send this script interrupted another client appointment, however. Given that I had already resent the script twice, I made the choice to interrupt the visit to send the script a third time.

This boy was without his medication for four school days. In this case, I was able to notify the school of the difficulty obtaining medication. The teacher, mother, student, and I made an emergency plan to help minimize problem behaviors in the school community while he was not taking medication. This required that I take additional time to contact all involved parties. The plan minimized transitions in the building, limited mainstream participation, and instead maximized academics being completed in the resource room with a 1:1 teaching assistant. While the plan decreases problem behaviors, it is not sustainable. It limits socialization and feels like a setback for a boy who had just made enough progress to move to a less restricted environment.

Case 3: I am a solo provider, and do not have a large office staff who can spend time calling pharmacies for me or filling in prior authorization forms, so the shortages have taken time away from my ability to care for the rest of my patients and/or the need to send and resend prescriptions is interrupting my day and evening hours. The shortage has caused severe stress for the parents, teachers, classmates and most importantly the children themselves.

Case 4: Parents are having problems locating Adderall for their kids. They are forced to call around to multiple pharmacies. When they locate the medication, they have to get in touch with me ASAP so that I can send in the script. I treat a lot of Medicaid patients in a community health clinic and I'm finding that it's increasingly difficult to get generic Adderall for my patients.

Case 5: I am licensed in California. I recently e-prescribed the patient's usual dose of Adderall IR (10mg twice a day) to their pharmacy, and the pharmacist informed the patient that they are not taking any new stimulant prescriptions for new patients because of the stimulant medication shortage. My most pressing concern is how to help my patient get their medication. I'm writing as this is hindering patient care, to determine if I have any other options regarding the prescription, and to ask where I can get more information about the stimulant shortage that is impacting patients/providers.

Case 6: The problem is widespread every day with one patient or another going without med/parent sending MyChart messages again frustrated they can't find supply/working with them to locate supply/calling around myself/eventually moving stabilized patients to another agent when parents have reached their limit on their monthly search process although new med may or may not also be in short supply now or in the future (and may not be effective)…it is a mess and creating significant unbillable MyChart message time and parents are spending huge amounts of time every month searching for supply…I try to stay optimistic this will improve soon but starting to lose hope. (Not being able to get any actual osmotic generic Concerta is also a BIG problem as many of my patients are not doing well on the non-osmotic Concerta; trying out the new Relexii if can get insurance to cover).

Case 7: Just this morning, I have a patient in longstanding remission from opioid use disorder who has ADHD and has been very successfully treated with a stimulant (Adderall XR) for over 5 years. He is fully employed and has been "sober." He has not been able to secure a prescription of Adderall XR easily—he has been shifted to immediate release Adderall, Dexedrine (spansules), and even methylphenidate. He feels very stressed with having to secure his stimulants to help him manage his position (high level position now), and notes going from pharmacy to pharmacy to find medication reminds him of his drug-use days. He notes that he has been so stressed at work and feels that his cravings and urges are returning; along with drug-like behavior as he drives from pharmacy to pharmacy to secure his supply of medication.

Case 8: 9-years-old with high functioning ASD after failed multiple medication trail, were finally stabilize with Adderall-XR with alpha-2 agonist. The family was not able to fill stimulant because of drug shortage, that child ended up coming to ED for worsening behavior and was admitted to inpatient. Other parent who had to take off one afternoon and had to call around pharmacies in the area to find the pharmacy, which they can fill prescription and father has to drive for an hour to get medication refilled.

Case 9: My latest example is a patient calling 2 weeks early in anticipation of trip out of town since it took so long the last time. We had to call 6 different pharmacies. I have easily over 200 people on ADHD treatment. About 50-60% of prescriptions cannot be filled for original amount and brand at first pharmacy.